

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademerk Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Weshington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKETT NO.
08/997,813	12/24/97	Fahey et al.	046528/0116/
•		•	EXAMINER
		i i	Jordan
			ART UNIT PAPER NUMBER
			1614 q
;		EXAMINER INTERVIEW SUMMARY RE	DATE MAILED:
All participants /applican	it, applicant's representati		55115
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(1) Dimberly	Jordan	(3) 320 0	0-1
(2) Paul 1	alalay	(4) Kicher	d set
Date of Interview	dornary 17.	1999 (5) Antony	Talalay
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Identification of prior art	discussed:		· · · · · · · · · · · · · · · · · · ·
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(A fullar description, if ne attached. Also, where re	cessary, and a copy of the	e amendments, if available, which the examiner ag s which would render the claims allowable is availa	need would render the claims allowable must be ble, a summary thereof must be attached.)
		a separate record of the substance of the Interview	
WAIVED AND MUST IN	CLUDE THE SUBSTANC	indicate to the contrary, A FORMAL WRITTEN RE E OF THE INTERVIEW (e.g., items 1-7 on the reve en one month from this interview date to provide a	SPONSE TO THE LAST OFFICE ACTION IS NOT rise side of this form). If a response to the last Office statement of the substance of the Interview.
Since the examination     regularements the	iner's interview summary at may be present in the last office a	above (including any attachments) reflects a compleast Office action, and since the claims are now allo	ete response to each of the objections, rejections and wable, this completed form is considered to fulfill the parate record of the substance of the interview unless
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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 046528/0116/JOHO

In re patent application of

Jed FAHEY et al.

Group Art Unit: 1610

Serial No. 08/997,813

Examiner: K. Jordan

Filed: December 24, 1997

For: CANCER CHEMOPROTECTIVE FOOD PRODUCTS

Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

The undersigned attorney of record hereby appoints Richardot, Registration No. 35,792 as associate attorney with full of association, substitution and revocation, to prove-identified application and transact all and Trademark Office connected relationship in the correspondence should med. C. Peet, Registration No. 35,792 as associate attorney with full power of association, substitution and revocation, to prosecute the above-identified application and transact all business in the Patent and Trademark Office connected therewith.

undersigned.

Respectfully submitted,

February 17, 1999

Bernhard D. Saxe Reg. No. 28,665

FOLEY & LARDNER Suite 500 3000 K Street, N.W. Washington, DC 20007-5109 (202) 672-5300



# UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED I	NVENTOR	· · · · · · · · · · · · · · · · · · ·	ATTORNEY POCKETING.
08/997,813	12/24/97	FAREY	— was-144		
FOLEY & LARD	VER	HM12/0301	٦	JORDAN,	EXAMINER
3000 K STREE SUITE 500 WASHINGTON DO		·		ART UNIT	PAPER NUMBER
				DATE MAILED:	03/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

	Application No. 08/997,813	Applicant(s)	Fahey et	al.
Notice of Allowability	Examiner	L	Group Art Unit	
	Kimberly Jore	ien	1614	
All claims being allowable, PROSECUTION ON THE MERI herewith (or previously malled), a Notice of Allowance an mailed in due course.	TS IS (OR REMAINS) ( d Issue Fee Due or oth	CLOSED In 1 ler appropri	this application. late communica	If not included attention will be
★ This communication is responsive to Paper Nos. 8-9	<del></del>			
∑ The allowed claim(s) is/are 48-57, 68, 69, and 72-79				<del>(-11</del>
☐ The drawings filed on are accept	otable.			
Acknowledgement is made of a claim for foreign prior	ty under 35 U.S.C. §	l 19(a)-(d).		
☐ All ☐ Some* ☐ None of the CERTIFIED copie	s of the priority docum	ents have i	been	
received.				
received in Application No. (Series Code/Serial N	Number)	·		
received in this national stage application from t	he International Bureau	(PCT Rule	17.2(a)).	·
*Certified copies not received:				
☐ Acknowledgement is made of a claim for domestic price	prity under 35 U.S.C.	119(e).		
A SHORTENED STATUTORY PERIOD FOR RESPONSE to THREE MONTHS FROM THE "DATE MAILED" of this Off ABANDONMENT of this application. Extensions of time in	ice action. Failure to t	imely comp	aly will result in	
☐ Note the attached EXAMINER'S AMENDMENT or NOT that the eath or declaration is deficient. A SUBSTITUTE	ICE OF INFORMAL AF	PLICATION	I, PTO-152, wh	
☐ Applicant MUST submit NEW FORMAL DRAWINGS				
because the originally filled drawings were declared	by applicant to be info	ırmal.		
<ul> <li>including changes required by the Notice of Draftsp to Paper No.</li> </ul>			PTO-948, attac	hed hereto or
including changes required by the proposed drawing approved by the examiner.	g correction filed on _		, whi	ch hás been
including changes required by the attached Examine	er's Amendment/Comr	nent.		
identifying indicle such as the application number (sea drawings. The drawings should be filed as a separate Draftsperson.	37 CFR 1.84(c)) show paper with a transmitt	ld be writte al lettter ac	n on the revers idressed to the	e side of the Official
☐ Note the attached Examiner's comment regarding REC	UIREMENT FOR THE I	DEPOSIT O	F BIOLOGICAL	MATERIAL.
Any response to this letter should include, in the upper rig CODE/SERIAL NUMBER). If applicant has received a Notic and DATE of the NOTICE OF ALLOWANCE should also be	ce of Allowance and is	PPLICATIO sue Fee Du	N NUMBER (SE le, the ISSUE B	RIES ATCH NUMBER
Attachment(s)				
Notice of References Cited, PTO-892				
☑ Information Disclosure Statement(s), PTO-1449, Pa	iper No(s). 6			
☐ Notice of Draftsperson's Patent Drawing Review, P	TO-948			
Notice of Informal Patent Application, PTO-152			1	
☐ Interview Summary, PTO-413			th. c	$\overline{z}$
Examiner's Amendment/Comment			1-	per
Examiner's Comment Regarding Requirement for D	eposit of Biological Ma	terial		BERLY JORDAN
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XM PTO-1449 (1	nodilisa)		,	ATTY DOCKET NO.		SERIAL NO. 08/987,813	
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			48589118 APPLICANTS		06/887,613		
LIST OF RÉFERENCES CITED BY APPLICAN (Vao soveréi shoots if necessary)		NTS	Jed FAHEY et al.	<del></del>	GROUP	· · · · · · · · · · · · · · · · · · ·	
ite Submitted to	PTO: J	nuary 11, 1999		December 24, 1997		1814	
<del></del>		·		U.S. PATENT DOCUMENTS			
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	· ·	OTHE	R DOCUMENT	(S) (Including Author, Title, Date,	Pertinent Pages	, Etc.)	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 503; Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicants

IPT-212(a):4/90



UNITED STATES DEPARTMENT OF COMMERCE AND ADDRESS OF THE STATES OF THE ST Patent and Trademark Office

# NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM1270301

FOLEY & LARDNER 3000 K STREET NW SUITE 500 WASHINGTON DC 20007-5109

	APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
12.2	08/997,813	12/24/97	020	JURDAN, K	1614 . 03/01/99
	First Named FAHEY,		35 U	SC 154(b) term ext. =	0 Days.

THE OF CANCER CHEMOPROTECTIVE FOOD PRODUCTS

1	ATTY & DOCKET NO.	BUBCLASS BATCH NO.	APF	LN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
	1 046528/0116/	424-094.100	P60	UTILIT	Y YES	\$605.00	06/01/99
	1 000000701101	424-054.100	1 00		, , , , , , ,		

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUETEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHAPE BEGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

# HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- If. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your tSSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "45" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All-communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance face when due.

> PTOL-85 (REV.-10-96) Approved for use through 06/30/99, (0651-0033)

PATENT AND TRADEMARK OFFICE COPY

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# IN THE UN. . AD STATES PATENT AND TRADE. .RK OFFICE

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In re application of

Group Art Unit:

1614

Jed FAHEY et al.

Examiner:

K. Jordan

Serial No.: 08/997,813

Atty. Dkt. No. 46585/116

Filed:

December 24, 1997:

CANCER CHEMOPROTECTIVE FOOD PRODUCTS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. S\$1.56, 1.97(c) and 1.17(p)

Assistant Commissioner for Patents Washington, DC 20231

Sir:

11031

Included with the attached Form PTO-1449 are documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. § 1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie prior art reference against the claims of the present application.

Applicants respectfully request that the documents be considered and made of record in the present application and that an initialled copy of form PTO-1449 be returned in accordance with M.P.E.P. §609.

Applicants submit this document under 37 C.F.R. \$1.97(e), before the mailing date of either a final action under §1.113 or of a Notice of Allowance under \$1.311. Accordingly, the fee set forth in \$1.17(p) of \$240 is attached, and it is believed that no additional fees are required. However, the Commissioner is

6/2/1999 MINISHe MENTH Drized to charge any deficiency or to credit any 01 FC:186

overpaymen Deposit Account No. 19-0741.

Respectfully submitted,

February 17, 1999 Date

Richard C. Peet Reg. No. 35,792

PEB 2 3 1999 MATRIX-CUSTOMER SERVICE CENTER

FOLEY & LARDNER 3000 K Street, NW, Suite 500 Washington, DC 20007-5109 (202) 672-5300

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# IN THE CLATED STATES PATENT AND TRADEMARK FICE

In re Application of: Jed FAHEY et al.

Serial No.: 08/997,813 Filing Date: December 24, 1997

: CANCER CHEMOPROTECTIVE FOOD PRODUCTS

Receipt is hereby acknowledged of the accompanying: Information Disclosure Statement Under 1.197(c); 1449; 3 references; Checkeyo. \$240.00; Associate Power of Attorney RCP:wh PH 1:51

046585/0116 Due: N/A



# UNITED STATES DE ATMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

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	Response to Rule 312		
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		KIMBERLY JORDAN PRIMARY EXAMINER	
		GROUP 1999-	
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FORM PTOL-271 (REV. 1/96)

# U.S. GPO: 1986-404-496/40514

ORM PTO 1449 (mo	diffed)			ATTY DOCKET NO. 046528/0116		NAL NO. 987,813	
• РА	TENT AND	MENT OF COMMERCE TRADEMARK OFFICE		APPLICANT Jed FAHEY et et.			
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PART 8—ISSUE FEE T	PANSMITTAL

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**Box ISSUE FEE** Assistant Commissioner for Patente Washington, D.C. 20231



MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

FILING DATE

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

HM12/0301

TOTAL CLAIMS TA RADE

Note: The cartificate of mailing below can only be used for domastic mailings of the lasue Fee Transmittd. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have to own certificate of realling. Certificate of Mailing

I horeby certify that this issue Fee Transmittal is being deposited with the United States Postel Sorvice with sufficient postage for first chass mail in an envelope addressed to the Box issue Fee address above on the date indicated below.

FOLEY & LARDNER 3000 K STREET NW SUITE 500 WASHINGTON DC 20007-5109

(Depositor's nume) (Signature)

DATE MAILED 03/01/99

(Date)

12/24/97 08/997,813 FAHEY,

PTCL-858 (PEV,10-96) Approved for use through 06/30/99. OMB 0651-0033

APPLICATION NO.

JORDAN, K 35 USC 154(b) term ext. =

EXAMINER AND GROUP ART UNIT

0 Days.

THEOF CANCER CHEMOPROTECTIVE FOOD PRODUCTS

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ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN, TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 046528/0116	5/ 424-094.	100 P6	o UTI	ITY YES	\$605.00	06/01/99
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The COMMISSIONER OF PATENTS A (Authorized Signature) Richard	ND TRADEMARKS IS reques	sted to apply the is	sue Fee to the ap	oplication identified above.		
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Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 046528/0116/JOHO

In re patent application of

Jed FAHEY et al.

Group Art Unit: 1614

Serial No. 08/997,813

Examiner: K. Jordan

Filed: December 24, 1997

For: CANCER CHEMOPROTECTIVE FOOD PRODUCTS

# SUPPLEMENTAL RESPONSE UNDER 37 C.F.R. § 1.111

Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

RECEIVED **Publishing Division** 

Applicants thank Examiner Jordan for APReO wholesies extended during an interview held at the USPTO on February 17, 1999. Following up on Examiner Jordan's request, we submit herewith a document discussed at the interview. interview, Dr. Paul Talalay reviewed the contents of his Rule 132 Declaration submitted with the Amendment and Request for Reconsideration filed January 25, 1999. Dr. Talalay discussed the properties of cruciferous sprouts obtained by the methods described in the instant application.

Dr. Talalay noted during the interview that cruciferous sprouts can be selected which contain high concentrations of anticarcinogenic Phase 2 inducer activity. These cruciferous sprouts also contain low levels of indole glucosinolates which have potentially carcinogenic Phase I inducer activity. references listed in the document attached herewith show that an indole glucosinolate designated indole-3-carbinol (I3C) enhances carcinogenesis in animal models. Indole glucosinolates are found in market-stage broccoli, but in very low concentrations in cruciferous sprouts.

Applicants also attach herewith an executed copy of Dr. Paul Talalay's Rule 132 declaration submitted with the Amendment and Request for Reconsideration filed January 25, 1999.

For the reasons discussed in the Amendment and Request for Reconsideration filed January 25, 1999, as well as those discussed above, it is respectfully asserted that the prior art does not teach or suggest methods for increasing the chemoprotective amount of Phase 2 enzymes in a mammal by administering certain cruciferous sprouts which contain high Phase 2 enzyme inducing potential and non-toxic levels of indole glucosinolates.

It is believed that all claims are in condition for allowance. Reconsideration of all rejections and a notice of allowance are respectfully requested. Should there be any questions concerning this application, Examiner Jordan is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Reg. No. 35,792

FOLEY & LARDNER Suite 500 3000 K Street, N.W. Washington, DC 20007-5109 (202) 672-5300

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No. 046585/0116

99 FEB 25 PH 2:45

In re patent application of

Jed FAHEY et al.

Serial No. 08/997,813

Filed: April 11, 1997

For: CANCER CHEMOPROTECTIVE FOOD PRODUCTS

### DECLARATION OF PAUL TALALAY UNDER 37 C.F.R. \$1,132

- I, Paul Talalay, being duly warned, hereby declare and say:
- 1. I am a citizen of the United States of America, and reside at 5512 Boxhill Lane, Baltimore, MD 21210.
- 2. I am John Jacob Abel Distinguished Service Professor, Department of Pharmacology and Molecular Sciences, Johns Hopkins University School of Medicine, Baltimore, Maryland 21205. I am a member of the National Academy of Sciences of the United States, a Member of the American Philosophical Society founded in Philadelphia for the promotion of useful knowledge, and a former Professor of the American Cancer Society.
- 3. I am a physician and medical scientist who has been involved for the last 20 years in devising chemical and dietary strategies for reducing the risk of human cancer.
- 4. I am a co-inventor named in U.S. application serial No. 08/997,813 ("the application"). In relation to the application, I have reviewed an Official Action, mailed September

- 24, 1998, and the prior art cited therein, and I make the following observations.
- I am a named inventor of U.S. Patent No. 5,411,986 ("the '986 patent"). The Examiner asserts that the claims of the instant application are obvious over the teachings of the '986 patent. However, the '986 patent fails to teach or suggest that broccoli sprouts, or other cruciferous sprouts, are a source of sulforaphane or phase 2 enzyme inducer activity.
- 6. Examples 2 and 3 of the '986 patent teach that broccoli is a source of sulforaphane. Market stage, mature broccoli was used in the experiments described in Examples 2 and 3 of the '986 patent. The '986 patent therefore fails to teach or suggest that broccoli sprouts, or other cruciferous sprouts are a source of sulforaphane or Phase 2 inducer activity. In fact, we were extremely surprised to subsequently find that broccoli and other cruciferous sprouts contain high concentrations of Phase 2 enzyme inducer activity.
- The claimed methods of the application provide food products that not only contain unexpectedly high levels of anticarcinogenic Phase 2 inducer activity, but also contain unexpectedly low levels of potentially carcinogenic Phase 1 enzyme inducer activity. The prior art reference relied on by the examiner does not teach or suggest these unexpected

attributes of the human food product made by the claimed methods. The sprouts and their extracts are therefore both qualitatively and quantitatively radically different in their content of enzyme inducer activities compared to mature, market stage vegetables.

There is a continuing proliferation of epidemiological studies that demonstrate an inverse relation between the quantity of vegetables consumed and the risk of cancer. Furthermore, several of these studies emphasize the protective effect of cruciferous vegetables, specifically, and demonstrate a dose dependence of the magnitude of the effect. Consumption of >425 g/wk of mature, market stage Brassica sp. reduces the cancer odds ratio to approximately 0.5 (50% risk reduction) for colon cancer in comparison to the consumption of <125 g/wk. Kune et al., Nutr. Cancer 9: 21-42 (1987). The odds ratios for colon cancer in relation to vegetable consumption was determined. Graham et al., J. Natl. Cancer Inst. 61: 709-714 (1978). Individuals who ate an average of 0-20, 21-40, 41-60 and more than 61 servings per month had odds ratios of 1.00, 0.66, 0.57 and 0.47 respectively. If one extrapolates the results of Graham, a 75% reduction in cancer risk would require consumption of perhaps 750 g (ca. 1.5 lbs.) of vegetables per day. The results of 7 cohort studies and 87 case-control studies have been summarized. See Verhoeven et al., Cancer Epid. Biomarkers & Preventions 5: 733-748 (1996). Cohort studies showed: inverse associations between the consumption of cabbage, cauliflower and broccoli and risk of lung cancer;

between consumption of brassica vegetables and risk of stomach cancer; between broccoli consumption and risk of all cancers taken together and between brassica consumption and the occurrence of second primary cancers. They conclude that a high consumption of brassica vegetables is associated with a decreased risk of cancer.

- It is impractical for most individuals to consume the large quantities of market stage broccoli or other vegetables to achieve maximum protection, because the quantity of fiber and other phytochemicals that need to be consumed can cause bowel irritation and/or flatulence.
- 10. Cruciferous sprouts and sprout extracts prepared according to the claimed methods provide 20 to 50-fold higher levels of Phase 2 enzyme inducer activity than mature market stage cruciferous vegetables. The data from Tables 1 and 3 of the application are summarized in APPENDIX Al attached hereto. A significant health benefit can be realized through ingestion of small quantities of cruciferous sprouts, or sprout extracts, prepared according to the claimed methods. The same health benefits can only be realized, if at all, through the ingestion of intolerably large quantities of market stage vegetables that contain significantly lower concentrations of anticarcinogenic Phase 2 inducer activity compared to the sprouts prepared according to the application.

- 11. For purposes of illustration, we determined in one experiment that 3 grams of 3-day old broccoli sprouts, or 150 milligrams of a lyophilized hot water extract made from 3-day old broccoli sprouts, contain the same quantity of Phase 2 enzyme inducer activity as 150 grams of mature market stage broccoli. Phase 2 enzyme inducer activity is measured in the Hepa 1clc7 murine hepatoma cells grown in 96 well microtiter plates according to the method of Prochaska et al., Anal. Biochem. 169: 328-336 (1988). One unit of Phase 2 enzyme inducer activity is defined as the amount that when added to a single microtiter well, doubles the quinone reductase activity. The quantity of mature market stage broccoli, sprouts and sprout extracts that must be consumed to realize the same health benefit (2-1/4 million units of anticarcinogenic Phase 2 enzyme inducer activity) is shown in APPENDIX A2 attached hereto.
- 12. The methods of the application also provide food products comprised of certain cruciferous sprouts and sprout extracts that do not contain significant levels of indole glucosinolates which generate Phase 1 inducers. Phase 1 enzymes (cytochromes P-450) functionalize compounds, usually by oxidation or reduction. Although one role of Phase 1 enzymes is to detoxify xenobiotics, several cytochromes P-450 activate procarcinogens to highly reactive ultimate carcinogens.

- 13. Attached hereto as APPENDIX A3 are graphs showing comparative paired ion chromatographs of broccoli sprouts and mature market stage broccoli. The paired ion chromatographs were prepared according to the method developed in our laboratory by Prestera et al., Anal. Biochem. 239: 168-179 (1996). Shaded peaks on the chromatograph represent glucoraphanin, glucoerucin, glucobrassicin and neoglucobrassicin, respectively. The former two glucosinolates are alkylthioglucosinolates with potent Phase 2 enzyme inducer activity and are the predominant glucosinolates found in sprouts. The latter two glucosinolates are indole glucosinolates which predominate in mature market stage broccoli.
- 14. Recent studies have shown that sulforaphane (the hydrolysis product of glucoraphanin which is the principal inducer precursor in sprouts) has a number of favorable properties with respect to its use as a chemoprotector. Sulforaphane inhibits mammary tumor formation in female Sprague-Dawley rats treated with single doses of dimethylbenzanthracene. Zhang et al., Proc. Natl. Acad. Sci. USA 91: 3147-3150 (1994). Sulforaphane shows exceedingly potent inhibitory activity against DMBA-induced neoplastic mammary lesions in mouse mammary gland explants in culture: 84, 56, and 34% inhibition at 1  $\mu$ M, 100 nM, and 10 nM concentrations, respectively. Gerhauser et al., Cancer Research 57: 272-278 (1997). Sulforaphane is not itself genotoxic (i.e., does not produce unscheduled DNA synthesis) but inhibits the genotoxicity of N-nitrosodimethylamine (NDMA) in Salmonella

typhimurium and NDMA-induced unscheduled DNA synthesis in mouse hepatocytes. Barcelo et al., Carcinogenesis 17: 277-282 (1996). Sulforaphane has the unusual property of inhibiting cytochrome P-450 type 2E1 which is involved in the metabolic activation of carcinogenic nitrosamines. Barcelo et al., Carcinogenesis 17: 277-282 (1996).

15. The indole glucosinolates do not give rise to isothiocyanates upon myrosinase hydrolysis because the indole isothiocyanates are unstable. One major degradation product is indole-3-carbinol which has attracted a great deal of recent attention. Although this compound exerts anticarcinogenic activity in some experimental tumor systems when administered before the carcinogen, it has obvious tumor-promoting properties if given after the carcinogen. Indole-3-carbinol has a number of other undesirable properties that raise questions with respect to the advisability of its use in chemoprotection. Thus, indole-3-carbinol is: (1) a very weak Phase 2 enzyme inducer; (2) is converted (especially at the acid pH prevailing in the stomach) to dimeric and trimeric condensation products that bind with very high affinity to the Ah receptor and thereby induce certain cytochromes P-450 that activate carcinogens, i.e., it is a bifunctional inducer that elevates both Phase 1 and Phase 2 enzymes; and (3) upon chronic administration indole-3-carbinol enhances carcinogenic activity. Such continuous administration represents a likely scenario in any chemoprotective strategy, and

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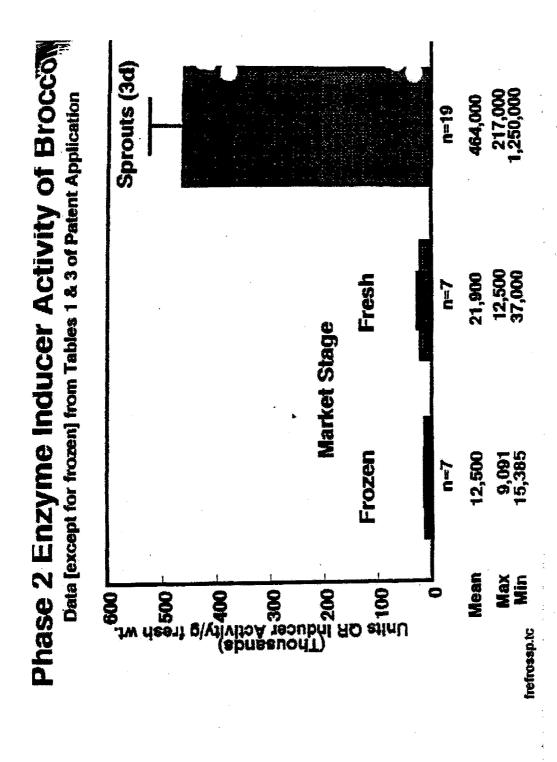
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Serial No. 08/997,813

indole glucosinolates are therefore not very desirable agents for these purposes.

16. The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

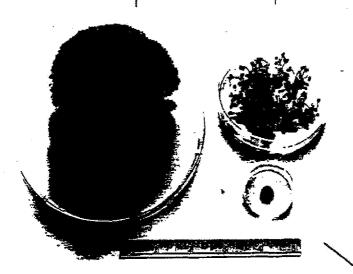
18 February 1999



# BROCCOLI

(150 GRAMS)

MARKET STAGE 3-DAY SPROUTS (3 GRAMS)

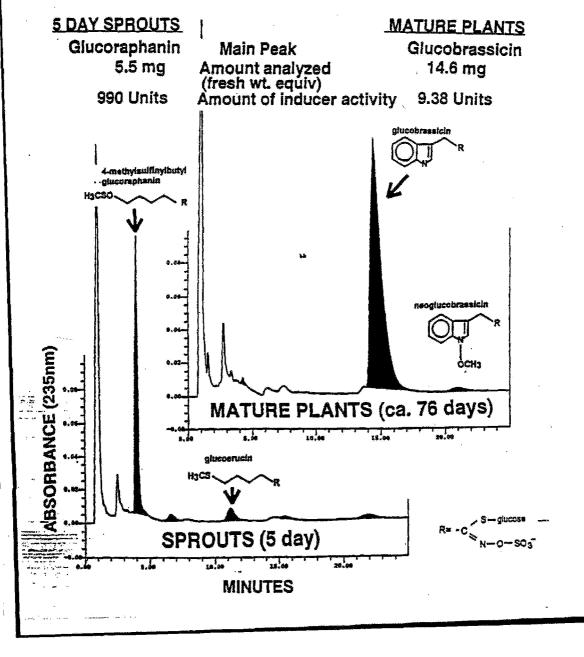


FREEZE DRIED WATER EXTRACT OF 3-DAY SPROUTS (150 MG)

ALL PREPARATIONS CONTAIN THE SAME QUANTITY (2-1/4 MILLION UNITS) OF ANTICARCINOGENIC **ENZYME INDUCER ACTIVITY** 

FIGURE 1

# PAIRED ION CHROMATOGRAPHY SHOWING GLUCOSINOLATE PROFILES OF BROCCOLI (cv. SAGA)





# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of

Jed FAHEY et al.

Serial No.: 08/997,813

Filed: December 24, 1997

Attorney Docket No.: 046585/0116

Allowed: March 1, 1999

Batch No.: P60

Group Art Unit: 1614

Examiner: K. Jordan

CANCER CHEMOPROTECTIVE FOOD PRODUCTS For:

## **LETTER**

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

The Issue Fee Transmittal, and payment of the Issue Fee filed on April 8, 1999 indicated that Applicant was a Small Entity with a \$605.00 Fee Due. Small entity status no longer applies to Applicant. Hence, Applicant encloses a check in the amount of \$605.00 to cover the Issue Fee payment as a large entity (\$1,210.00).

05/05/1999 SSANDAR1 00000015 08997813

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605.00 OP

Respectfully submitted,

Reg. No. 35,792

Foley & Lardner

3000 K Street, N.W., Suite 500 Washington, D.C. 20007-8696

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002.199987.1



# UNITED STATES LUPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

DATE MAILED:

ļ	APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT			7
	US/997	.813 12/	24/97 FAHEY		J 046528/0	 7.16

FOLEY & LARDNER 3000 K STREET NW SUITE 500 WASHINGTON DC 20007-5109

HM42/0520

EXAMINER JORDAN, K ARTUNIT PAPER NUMBER 1614

05/20/99

Response to Rule 312

Communication

The patition filedunder 37 CFR forwarded to the examiner for consideration on the merits.	1,312(b) is granted. The paper has been
	Director, Patent Examining Group
Supplemental  The amendment filed February 26, 1999  considered, and has been:	under 37 CFR 1.612 has been
<ul> <li>entered.</li> <li>entered as directed to matters of form not affecting the scop</li> <li>disapproved. See explanation below.</li> </ul>	be of the invention (Order 3311).
entered in part, See explanation below.	÷
j P	KIMBERLY JOHOAN RIMARY EXAMINER

GROUP 1200-1610

FORM PTOL-271 (REV. 1/96)

# U.S. GPO: 1998-404-498/40514

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 046585/0116

In re patent application of

Case 1:07-cv-07844-SAS

Jed FAHEY et al.

Filed: December 24, 1997

Allowed: March 1, 1999

Batch: P60

Group Art Unit: 1614

Examiner: K. Jordan

For: CANCER CHEMOPROTECTIVE FOOD PRODUCTS

# INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

RECEIVED Publishing Division

NOV 3 0 1999

TECH4

Submitted herewith on a modified Form PTO-1449 is a listing of documents known to applicant in order to comply with applicant's duty of disclosure pursuant to 37 C.F.R. §1.56, and in view of MPEP § 2001.06(c). The listed documents became know to applicant incident to a suit for infringement of U.S. Patent No. 5,725,895 filed in the District Court of Delaware. The above-captioned patent application is a divisional of the patent application which issued as U.S. Patent No. 5,725,895.

The accompanying Form PTO-1449 lists several papers and publications that were provided during the course of discovery in the infringement suit. In addition, the defendants have recently filed a request for reexamination of U.S. Patent No. 5,725,895 citing several of the listed papers and publications. A copy of the request for reexamination is provided herewith.

Applicant believes that the documents listed in the accompanying Form PTO-1449 do not adversely impact the patentability of the claims of the above-captioned application. However, out of an abundance of caution, and in compliance with the duty of disclosure, applicant hereby brings these documents to the attention of the Patent Office.

In the course of the infringement suit, the defendants also have lodged several affirmative defenses and counterclaims, including (1) invalidity and unenforceability for failure to comply with the provisions of 35 U.S.C. §§ 101, 102, 103, and 112, (2) breach U.S. Serial No. 08/997,813

Attorney Docker No. 046585/0116

Filed 05/09/2008

of the duty to disclose material information, and (3) patent misuse. Provided herewith is a copy of the defendants' "Answer, Affirmative Defenses and Counterclaim," which contains these allegations.

Applicant believes that the foregoing affirmative defenses and counterclaims are without merit. However, out of an abundance of caution, and in compliance with the duty of disclosure, applicant hereby brings these documents to the attention of the Patent Office.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present patent or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie prior art reference against the claims of the present patent.

Since a Notice of Allowance has been mailed in this application, it is respectfully requested that this Information Disclosure Statement and the listed documents be placed in the file of the present application, pursuant to 37 C.F.R. §1.97(i).

Respectfully submitted,

October 19, 1999

Date

Registration No. 35,792

FOLEY & LARDNER 3000 K Street, NW, Suite 500 Washington, DC 20007-5109 (202) 672-5300

If there are any fees due which are not enclosed herewith, including any fees required for an extension of time, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account Number 19-0741.

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IEET 1 of 2 IRM PTO 1449 (modified)	ATTY DOCKET NO 1 D SERIAL NO.
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te Submitted to PTO: October 19, 1999	December 24, 1997 (1997) 1614
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FORM PTO 1449 (modified)	ATTY DOCKET NO. 046585/0116 O P E 08/977,813						
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	046585/0116 OIPE 08/977,813						
LIST OF REFERENCES CITED BY APPLICANT(S	APPLICANT						
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OTHER DOCUMEN	F(S) (Including Author, Title, Date, Pertinent Pages, Etc.)						
The Sp	routletter, Number 29, July - August 1985.						
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dated September 20, 1999.							
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	outman, Inc.'s Answer, Affirmative Defenses and Counterclaims dated June 28, 1999						
Request	for Reexamination of U.S. Patent No. 5,725,895 filed October 11, 1999						
EXAMINER	DATE CONSIDERED						

\*PEXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT APPLICATION SERIAL NO.

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FEE RECORD SHEET

PTO-1556 (5/87)

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Title:
  Preliminary ammendments all entered. Check back of file.
  Full disclosure read - including 1449:
  Art Classified - use 1449 and background of disclosure.
  Brief Application & mark it on wrapper.
 Shoes searched - write it down on the file wrapper!
               V CAS searched. - work it on wrapper
     Insert serial # (07/---, ---) and AU.

    Claims 1 - 7 are presented for examination . . . 01

M Restriction to one of the following . . . 8.08
The amendment received on -/-/-- has been entered. . .
Acknowledge any priority 2.18 - 2.26.
تنكر Title 6.11.
Oath - esp. citizenship. address and signatures 6.05.
 Abstract - length, compnds used, improp. lang. 6.12-.16
Informal Drawings 6.22-6.27
1125: 1st. 2hd & 4th. (07.32 (2)7.34
    102s & 103s: check for type of utility. 7.20, 7. 20. 2, 7. 2
    Note other references 7.96-01
No claims allowed: / Contact Dr. Gary 7-96-02-
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## CODE SHEET FOR CONTINUING DATA

Line	Code	Serial No.	Fiting Date			Issue Date
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### Condition and Status Codes for Continuing Data

# CONDITION CODE

71	Continuation of application No.
81	which is a continuation of application No.
91	and a continuation of application No.

72 82 75 Continuation-in-part of application No. which is a continuation-in-part of application No. and a continuation-in-part of application No.

74 84 76 Division of application No. which is a division of application No. and a division of application No.

, said application No. Application No. and application No. each 86 89 90 92

tileo as application No. Substitute for application No. Provisional application No. 66 68

# STATUS CODE

01 03 04 Patent No. abandoned SIR No.

NOTE I: When the codes 86 and 92 are used, they must be followed by 81, 82 or 84 - conditions beginning with "which is"

NOTE II: Codes 71, 72 and 74 may be used only on the first line; one of them <u>must</u> be used on the first line in segular continuing data. 86 or 68 may be used on the first line in Substitute or Provisional cases. Remember, however, that if there is a Provisional and other continuing data, the Provisional is always tisted tast.

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PATENT APPLICATION FEE DETERMINATION RECO							Application or Docket Number 998/3				r		
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IRM PTO-875 (Rev. 6/97)

\*U.S. Government Printing Office: 1997 - 430-571/69194

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE